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EQUITY RESEARCH
Company Report

August 15, 2017

Asterias Biotherapeutics (AST - $3.25)

Healthcare/Biotechnology

2Q17: Uneventful Earnings Call with Cohort Five Enrollment Started and Critical Data Readouts in 4Q17 and 1Q18

Ticker:	**AST**
Rating:	**Buy**
Price Target:	**$12.00**

Yesterday after the market close, AST reported 2Q17 financial results with a net loss of ($8.7MM) vs. Laidlaw ($7.7MM) and the Street ($8.7MM) estimates. Net loss/share was ($0.18) vs. ($0.16) and ($0.18) for Laidlaw and the Street. AST ended 2Q17 with $25 MM cash, sufficient to support operations into 1H18, in our opinion.

- **SCiStar study updates.** AST reported that the patient enrollment and dosing of $10x10^6$ AST-OPC1 cells in AIS-B SCI cohort (n=5) and $20x10^6$ AST-OPC1 cells in AIS-A SCI cohort (n=5) have completed, with top-line six-month follow-up results expected in January 2018. Safety, improvements of upper extremity motor score (UEMS), and motor level (by ISNCSCI examinations) are the major endpoints. In addition to motor function improvement, potential improvements of sensory function (also by ISNCSCI) in AIS-B SCI patients can also be examined. Enrollment and dosing of the $20x10^6$ AST-OPC1 cells in AIS-B SCI cohort started in mid-3Q17, and AST expects completion of patient recruitment of this cohort before year end 2017. Further, two more clinical sites, Thomas Jefferson University Hospital in Philadelphia, and UC San Diego Health in San Diego, were added to the SCiStar study earlier this month. Together, we view the SCiStar study is progressing well with catalysts of critical data readout slate to 4Q17 (possibly in late 3Q17 for 12-month follow-up results of AIS-A SCI $10x10^6$ cells cohort) and 1Q18. Should the outcome be positive, AST plans to conduct more formal discussions with the FDA, possibly in 1Q17, to map out the future Phase IIb and possibly pivotal trials to advance the OPC1 program forward.
- **Phase IIb trial could start in 2H18.** Should the ongoing SCiStar trial show a promising outcome and receive more FDA feedback, AST could start a placebo-controlled Phase IIb trial in 2018, possibly in mid- to 2H18. AST could potentially incur much less costs for the study if they apply for and successfully receive funding support from the California Institute of Regeneration Medicine (CIRM).
- **Action.** We are reiterating our Buy rating and $12 target price. Our valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses. We believe AST shares are undervalued given its differentiated and promising SCI treatment modality, and potentially positive multiple catalysts in next 18 months.

Trading Data:

Last Price (8/14/2017)	$3.25
52–Week High (11/18/2016)	$5.80
52–Week Low (8/26/2016)	$2.54
Market Cap. (MM)	$163
Shares Out. (MM)	42.934

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.13A	-0.18A	-0.16	-0.18	-0.65	N.A.
FY-16A	-0.27	-0.12	-0.24	-0.20	-0.83	N.A
FY-15A	-0.09	-0.10	-0.09	-0.13	-0.42	N.A.
FY-14A	-0.07	-0.09	-0.05	-0.11	-0.33	N.A.

Source: Laidlaw & Company estimates

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- **AST-VAC1 and AST-VAC2 updates**. AST indicated that the additional improvements of the AST-VAC1 process will be slowed down near term in order to better utilize resources for other programs. Cancer Research UK along with AST recently have completed the manufacture of the first cGMP clinical grade lot of AST-VAC2 material and is ready for the upcoming Phase I/IIa study in non-small cell lung cancer; which we believe will start in 3Q17 with possible initial data readout starting in 2018.

Table 1: Estimated and reported 2Q17 results

2Q17 Estimates and Reported Results			
($,000)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$1,830**	**$316**	**$1,400**
Total op. profit (loss)	**($9,866)**	**($8,831)**	**($8,600)**
R&D	($7,410)	($6,984)	
SG&A	($2,456)	($1,847)	
EPS	**($0.16)**	**($0.18)**	**($0.18)**
Net income (loss)	($7,683)	($8,728)	($8,700)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
AST-OPC1	Subacute spinal cord injury (SCI) cervical complete (AIS-A at C5-C7)	Report 10MM cell 12-month results	**4Q17**	****
		Report 20MM cell 6-month results	**Jan. '18**	****
		Report 20MM cell 12-month results	**4Q18**	***
	Subacute spinal cord injury (SCI) cervical incomplete (AIS-B at C5-C7)	Report 10MM cell 6-month results	**Jan. '18**	****
		Complete patient enrollment of 20MM cell trial	**1Q18**	***
		Report 10MM cell 12-month results	**4Q18**	****
		Report 20MM cell 6-month results	**3Q18**	****
	Subacute spinal cord injury (SCI) cervical	More formal discussion with the FDA for possible Phase II and III trial	**1Q18**	***
		Potentially finalize Phase IIb trial design after FDA discussion	**1H18**	***
		Potentially start Phase IIb trial	**2H18**	***
AST-VAC1	Acute myeloid leukemia (AML)	Potentially start Phase IIb confirmatory trial	**2018**	***
AST-VAC2	Non-small cell lung cancer (NSCLC)	Potentially start Phase I/IIa trial	**3Q17**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company and company presentation

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Major Risks

Clinical study failure could have a major impact on AST share value. Despite promising pre-clinical and clinical results of the company's lead product, AST-OPC1, it remains too early to predict the long-term safety and efficacy outcomes from the upcoming clinical studies. Given that clinical validation has not been fully established, near term, it would be critical for the additional studies of the ongoing Phase I/II trial to demonstrate efficacy and a positive safety profile after a longer follow-up, higher dosage and broader patient population in order to increase the assets and shareholder value. Negative results of ongoing and future clinical studies could have a materially negative impact on the shareholder value; especially since the company has a relatively diverse-limited pipeline profile. In addition, given there has been very limited progress over the last two decades in developing therapeutics for treating SCI, the overall risks in developing an effective treatment in this area could be higher than in other disease areas.

Yet-to-be-validated pluripotent stem cell platform could remain uncertain. Although stem cell-based therapies have been tested in many clinical trials in recent years; there is currently no pluripotent stem cell-based therapy approved for the treatment of spinal cord injury or other disease indications. As such, clinical risks for pluripotent stem cell-based therapies are higher than similar products generated from other more proven development platforms.

Product may not be approved or reach anticipated sales. Although AST's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and the possible changes in pricing flexibility that could potentially have a negative impact on payer reimbursement. Other potential commercial risks also include the societal or political pressure that could limit premium pricing capability for many orphan drugs moving forward. Further, a below expectation revenue outlook could also negatively affect AST shareholder value.

Additional financings could dilute shareholder value. Although the company currently has ~$34MM total cash as of the end of February 2017, AST would most likely need more financial resources going forward if they want to expand and further develop their pipeline unless the company can continuously explore un-dilutive financial sources. Should the future operational expenses significantly increase, especially in the areas of R&D and SG&A, products not receive FDA approval, or product revenue not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

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Figure 1: Income Statement

Asterias Biotherapeutics – Income Statement

($'000)	2014	2015	2016	1Q17	2Q17	3Q17E	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue																
AST-OPC1 US sales													10,466	30,891	79,246	174,950
AST-OPC1 ex-US royalties and COGS													0	0	3,338	14,931
AST-OPC1 total revenue													**10,466**	**30,891**	**82,584**	**189,881**
AST-VAC1 in AML revenues															37,131	95,994
AST-VAC2 in NSCLC revenues																85,629
Total product revenues													10,466	30,891	119,714	371,505
Royalties from product sales	189	535	381	116	25	89	159	389	416	433	450	468	487	506	527	548
Sale of cell lines		40	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grant income	1,034	3,007	6,572	1,894	291	1,500	70	3,755	3,905	4,061	4,224	4,393	4,569	4,751	4,941	5,139
Total revenue	1,224	3,582	6,953	2,010	316	1,589	229	4,144	4,321	4,494	4,674	4,861	15,522	36,149	125,182	377,192
COGS of therapeutic products													(2,093)	(6,178)	(24,489)	(76,744)
Cost of sales	(95)	(268)	(127)	(53)	(18)	(37)	(67)	(175)	(175)	(182)	(189)	(197)	205	(5,966)	(24,268)	(76,514)
Total gross profit	1,129	3,314	6,826	1,957	298	1,552	162	3,969	4,147	4,312	4,485	4,664	15,726	36,857	106,852	266,396
Expenses																
Research and development	(13,310)	(17,321)	(25,468)	(6,598)	(6,984)	(7,005)	(7,075)	(27,662)	(31,811)	(37,855)	(45,805)	(53,592)	(57,343)	(59,637)	(57,848)	(52,063)
General and administrative	(5,280)	(7,901)	(15,481)	(4,466)	(1,847)	(1,884)	(1,908)	(10,105)	(10,914)	(11,896)	(12,848)	(13,747)	(14,434)	(15,156)	(15,914)	(16,710)
Marketing and sales													(20,000)	(25,000)	(29,250)	(31,298)
Total operating costs and expenses	(18,590)	(25,222)	(40,949)	(11,064)	(8,831)	(8,889)	(8,983)	(37,767)	(42,725)	(49,751)	(58,653)	(67,339)	(91,778)	(99,793)	(103,012)	(100,070)
Operating Incomes (losses)	(17,461)	(21,908)	(34,123)	(9,107)	(8,533)	(7,337)	(8,821)	(33,798)	(38,578)	(45,439)	(54,168)	(62,675)	(76,051)	(62,936)	3,840	166,325
Other Income/(Expense)																
Change in fair value on warrant liability			(3,107)	2,954	(56)	(349)	(450)	2,099	(2,100)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)
Interest expense, net	(10)	(341)	(548)	(134)	(114)	(207)	(240)	(695)	(730)	(1,599)	(1,598)	(1,597)	(1,629)	(1,662)	(1,695)	(1,729)
Other income (expense), net	(2)	(6)	(36)		(25)	40	50	65	72	79	87	95	105	115	127	139
Total other income (expense), net	(12)	(347)	(3,691)	2,820	(195)	(516)	(640)	1,469	(2,758)	(2,720)	(2,711)	(2,702)	(2,724)	(2,746)	(2,768)	(2,789)
Pretax income	(17,473)	(22,255)	(37,814)	(6,287)	(8,728)	(7,853)	(9,461)	(32,329)	(41,337)	(48,159)	(56,879)	(65,376)	(78,776)	(65,683)	1,072	163,536
Deferred income tax benefit	7,376	7,252	2,324	0	0	0	0	0	2,789	2,860	2,860	2,860	2,860	2,860	(397)	(60,508)
Net Income (Loss)	**(10,097)**	**(15,003)**	**(35,490)**	**(6,287)**	**(8,728)**	**(7,853)**	**(9,461)**	**(32,329)**	**(38,548)**	**(45,299)**	**(54,019)**	**(62,516)**	**(75,916)**	**(62,823)**	**675**	**103,028**
Basic and diluted net loss per share	($0.33)	($0.42)	($0.83)	($0.13)	($0.18)	($0.16)	($0.18)	($0.65)	($0.71)	($0.79)	($0.89)	($1.00)	($1.12)	($0.93)	$0.01	$1.52
Weighted average common shares outstanding: basic and undiluted	30,720	35,443	42,943	48,357	48,511	48,551	52,551	49,493	54,493	57,493	60,493	62,493	67,493	67,593	67,693	67,793
Margin Analysis (% of Sales/Revenue)																
Costs of goods	-50%	-50%	-33%	-42%	-42%	-42%	-42%	-45%	-42%	-42%	-42%	-42%	-42%	-42%	-42%	-42%
R&D	-1088%	-484%	-366%	-328%	-2210%	-441%	-3090%	-668%	-736%	-842%	-980%	-1102%	-369%	-165%	-46%	-14%
SG&A	-431%	-221%	-223%	-222%	-584%	-119%	-833%	-244%	-253%	-265%	-275%	-283%	-93%	-42%	-13%	-4%
Operating Income (loss)	-1427%	-612%	-491%	-453%	-2700%	-462%	-3852%	-816%	-893%	-1011%	-1159%	-1289%	-490%	-174%	3%	44%
Pretax	-1428%	-621%	-544%	-313%	-2762%	-494%	-4132%	-780%	-957%	-1072%	-1217%	-1345%	-508%	-182%	1%	43%
Tax Rate													37%	37%	37%	37%
Net Income	-825%	-419%	-510%	-313%	-2762%	-494%	-4132%	-780%	-892%	-1008%	-1156%	-1286%	-489%	-174%	1%	27%
Financial Indicator Growth Analysis (YoY%)																
Total Revenue	NA	193%	94%	26%	-79%	-23%	-87%	-40%	4%	4%	4%	4%	219%	133%	246%	201%
R&D	NA	30%	47%	4%	16%	34%	-10%	9%	15%	19%	21%	17%	7%	4%	-3%	-10%
SG&A	NA	50%	96%	-29%	-28%	-55%	-20%	-35%	8%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)	NA	25%	62%	-12%	3%	-6%	-13%	-8%	13%	16%	18%	15%	36%	9%	3%	-3%
Pretax Income	NA	27%	70%	-44%	56%	-32%	0%	-15%	28%	17%	18%	15%	20%	-17%	-102%	15160%
Net Income	NA	49%	137%	-39%	69%	-26%	1%	-9%	19%	18%	19%	16%	21%	-17%	-101%	15160%
EPS	NA	29%	97%	-52%	46%	-31%	-11%	-22%	8%	11%	13%	12%	12%	-17%	-101%	15137%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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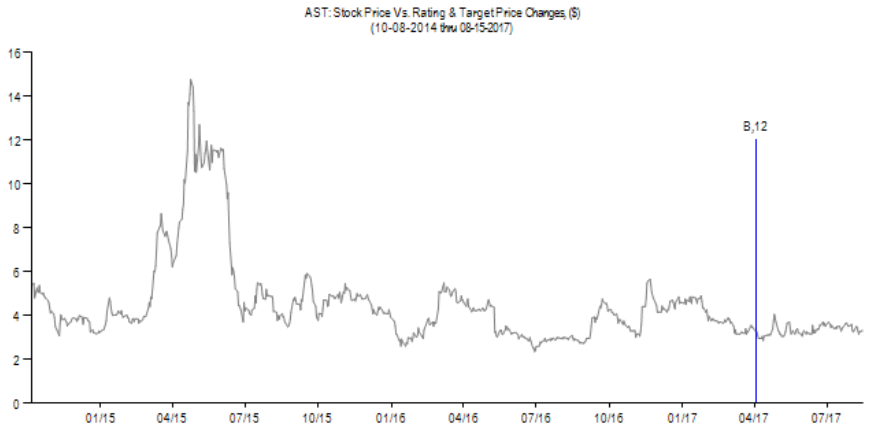

3 Year Rating Change History

Date	Rating	Closing Price ($)
04/03/2...	Buy (B)	3.25

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/03/2...	12.00	3.25

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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